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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,775	12/28/2001	Richard L. Goode	2401.0268C	6421
7590	12/13/2004		EXAMINER	
EPSTEIN & GERKEN 1901 RESEARCH BOULEVARD SUITE 340 ROCKVILLE, MD 20850-3164			EASHOO, MARK	
			ART UNIT	PAPER NUMBER
			1732	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/028,775	Applicant(s) GOODE ET AL.	
	Examiner Mark Eashoo, Ph.D.	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-20, 22 and 24 is/are allowed.
- 6) ☒ Claim(s) 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 23 is rejected under 35 U.S.C. 102(b) as being unpatentable over Hirsch et al. (US Pat. 5,080,650) when taken with Vance, Jr. (*Insert Molding* - Article) and the Dictionary.com definition of "flange" or alternatively under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al. (US Pat. 5,080,650) in view of Bodicky (US Pat. 4,354,495), Vance, Jr. (*Insert Molding* - Article), and the Dictionary.com definition of "flange".

Regarding claim 23: Hirsch et al. teaches the claimed process of making a medical ventilation tube, comprising: forming a hollow tubular shaft (elements 21, 42, 57) having rigidity and resists bending while in use (5:61-6:27 and Fig. 10); and forming a flange by onto the hollow tubular shaft using a material that has less rigidity than that of a first material in the hollow tubular shaft (4:11-43 and Fig. 3 and 8). Hirsch et al. teaches that the hollow tubular shaft has a durometer in the range of 30-40 Shore A (6:10-17) and that the flexible connection flange portions have a durometer of 10-40 Shore A (4:31-39). Since the hardness range of the flange extends well below that of the tube, Hirsch et al. meet the instantly claimed limitation directed to material hardness.

Hirsch et al. specifically recites that the flanges and tubular portion may be attached to one another by insert molding (4:58-62). Furthermore, Hirsch et al. states that a two stage molding process (ie. a two stage insert molding process) is used to connect the 2-piece retaining element of figures 1-5 to the tube (4:1-6). Vance Jr., provides evidence that it is inherent that 'insert molding' is a molding technique where a preform is inserted into a mold and another material is injection molded to encapsulate a portion of the preform. Vance Jr. states that insert molding is used quite extensively

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in the manufacture of medical devices, such as "insert molded needles hubs". A person having ordinary skill in the art would clearly understand that the hub is by the injected material. It is also noted that the flange structure of Hirsch et al. encapsulates an end portion of a tube (Fig. 3 and 8) and therefore a mold would inherently have a corresponding shape to hold a tubular preform and form the desired flange shape. In other words, it is inherent that the tube completely occupies a portion of a mold that is occupied by the shaft/tube and that before injection molding the flange/retaining element there is an unoccupied portion of the mold that corresponds to the shape of flange/retaining element.

It is noted that Hirsch et al. refers to the over all retaining element of figures 1-5 as comprising petaloid flanges and connecting portions (3:44-47). However, this is merely a choice of terminology used by Hirsch et al. and does not diminish the function of the overall "retaining element". The common meaning of the instantly claimed term "flange" is evidenced by the Dictionary.com definition of "flange" which states: "a protruding rim, edge, rib, or collar, as on a wheel or a pipe shaft, used to strengthen an object, hold it in place, or attach it another object". In this instance the overall retaining element of Hirsch et al. fits the common definition of "flange". Hirsch et al. also suggests that the greater surface area of the connecting portions aids in its operative function (3:44-63). Therefore, the connecting portions act as a "flange" or in this case part of the overall flange/retaining element and meets the instant limitation wherein a flange is made of material having a rigidity less than that of a tube portion.

Alternatively, if Hirsch et al. does not teaches forming a flange by molding onto a hollow tube, then Bodicky teaches molding a hub over a tube that has been inserted into a mold (Fig. 1 and 2:49-65). Hirsch et al. and Bodicky are combinable because they are both concerned with a similar technical difficulty, namely, connecting a plastic member to a plastic tube. At the time of invention a person having ordinary skill in the art would have found it obvious to have connected a molded

portion to a tube, as taught by Bodicky, in the process of Hirsch et al., and would have been motivated to do so since Bodicky suggest such molding step provides a secure and fluid tight connection between plastic parts. It is noted that Vance, Jr. teaches that various forms of bonding can be used in insert molding (mechanical and molecular) and that for molding similar materials, as in the case of Hirsch et al. (4:31-39 and 4:51-55), molecular bonding alone would suggest a reasonable chance of success. It is noted that this type of molding would apply to both stages in the molding process of Hirsch et al.

Bodicky teaches molding about a tubular preform (Fig. 1 and 2:49-65) to form a desired structure (ie. a hub). A person having ordinary skill in the art would find it obvious to use a mold in the shape of a flange portion in order to form the structure of Hirsch et al. Hirsch et al. and Bodicky would be combined for the reasons as set forth above. It is noted that Vance, Jr. teaches that various forms of bonding can be used in insert molding (mechanical and molecular) and that for molding similar materials, as in the case of Hirsch et al. (4:31-39 and 4:51-55), molecular bonding (ie. thermal bonding) alone would suggest a reasonable chance of success.

Response to Arguments

Applicant's arguments with respect to claim 23 have been considered but are moot in view of the new ground(s) of rejection. However, the following comments apply:

A) Applicant's argument alleges that a rejection under 35 USC § 102(b) made with multiple references is improper. However, such argument is incorrect and multiple references may be used in 35 USC § 102 rejections (see MPEP § 2131.01) in certain circumstances. In the rejection as set forth above, Vance Jr. is applied to show an inherent characteristic of "insert molding". Insert molding is taught by Hirsch et al. as set forth in the rejection. Similarly, the Dictionary.com reference is used to explain the meaning of the terms "connecting portions and retaining element" in

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the primary reference as compared to the instantly claimed term "flange". Since, the above reasons for using each references falls under the certain circumstances as set out in MPEP § 2131.01, the rejection made under 35 USC § 102(b) is proper.

Allowable Subject Matter

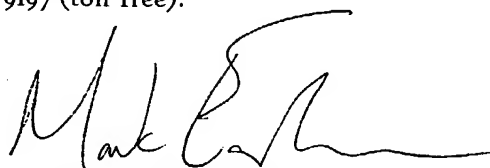
Claims 15-20, 22, and 24 are allowed for the reasons as argued in applicant's response filed 04-NOV-2004.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Eashoo, Ph.D. whose telephone number is (571) 272-1197. The examiner can normally be reached on 7am-3pm EST, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaanni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Eashoo, Ph.D.
Primary Examiner
Art Unit 1732

December 11, 2004
me

11/Dec/04